



UNITED STATES PATENT AND TRADEMARK OFFICE

19
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,698	07/03/2003	Bhiku G. Patel	03-40102-US	7194
<div>7590 10/17/2007 William J. McNichol, Jr., Esquire Reed Smith LLP 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301</div>			<div>EXAMINER GHALI, ISIS A D</div> <div>ART UNIT 1615</div> <div>MAIL DATE 10/17/2007</div> <div>PAPER NUMBER</div>	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED
OCT 17 2007
GROUP 1600

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/613,698
Filing Date: July 03, 2003
Appellant(s): PATEL ET AL.

TAMARA J. YORITA

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 06, 2007 appealing from the
Office action mailed October 25, 2006.

The receipt is acknowledged of appellants' IDS filed 07/06/2007. Initialized and signed 1449 form is attached to this examiner's answer.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

Art Unit: 1615

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,562,642	SMITH ET AL.	10-1996
6,183,766	SINE ET AL.	02-2001
6,784,145	DELAMBRE ET AL.	08-2004
6,338,855	ALBACARYS ET AL.	01-2002

(9) Grounds of Rejection

The following rejection has been withdrawn:

Issue 1:

The rejection of claims 1, 2, 5-18, 34, and 35 under 35 U.S.C. § 112, first paragraph as not complying with the written description requirement.

The following ground(s) of rejection are applicable to the appealed claims:

Issue 2:

The rejection of claims 1, 2, 6, 7, and 14-18 as being unpatentable under 35 U.S.C. §102(b) over the '642 Patent.

US '642 discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34). The active ingredients include benzoyl peroxide, which is inherently insoluble, and antibiotic including neomycin, clindamycin, erythromycin, or cortisone which read on claim 17-18 (col.10, lines 46-52). The composition is an emulsion (col.14, lines 38-40; table VI; col.20, lines 15-35). The pad is contained in a container comprising aluminum foil layer in contact or sealed with thermoplastic layer that is sealable by heat, which packaging is not prone to premature rupture but provides ready dispensing of the package contents (col.3, lines 55-57; col.8, lines 45-59). The pad can be impregnated by antifungal agent or other dermatologically active agents (col.11, lines 50-52). Viscosity is inherent to a specific composition.

Issue 3:

The rejection of claims 1, 2, 6, 7, 14, and 16-18 as being unpatentable under 35 U.S.C. §102(b) over the '766 Patent.

US '766 discloses non-woven pad impregnated by composition in the form of emulsion comprising: benzoyl peroxide (col.12, line 56); glycerin (col.11, line 42); antifungal agent (col.12, line 64); and glycerin, perfumes, erythromycin, which reads on claims 17-18 (col.11, lines 47; col.12 lines 17, 58-59; col.13, lines 44-45). The pads are

Art Unit: 1615

contained in a container (col.17, lines 41-45). The preferred droplet size of the emulsion is from 0.2 to 200 microns (col.4, lines 24-28). Viscosity is inherent to a specific composition.

Issue 4:

The rejection of claims 3-5, 8-13, 34, and 35 as being unpatentable under 35 U.S.C. §103(a) over the '642 Patent.

The teachings of US '642 are discussed above. US '642 does not teach the BPO in an emulsion, the claimed particle size and viscosity, or the woven material.

US '642 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the invention would have been motivated to include BPO in the emulsion of table VI, motivated by the skill of versed artisan that BPO is effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is delivered cutaneously and effective against acne.

The claimed particle sizes and viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests the low viscosity of the liquid composition as implied by the flowability of the composition in order to be absorbed into the non-woven pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain flowability of the composition suitable for the composition to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

Issue 5:

The rejection of claims 3-5, 8-13, 34 and 35 as being unpatentable under 35 U.S.C. §103(a) over the '766 Patent.

The teachings of US '766 are discussed above. US '766 does not teach the BPO in an emulsion, the claimed viscosity, or the woven material.

US '766 suggests the use of BPO for skin application from a pad and also suggests the emulsion. Therefore, one having ordinary skill in the art at the time of the invention to include BPO in the emulsion, motivated by the skill of versed artisan that BPO is effective antimicrobial agent and effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is effective against bacteria and acne.

Art Unit: 1615

The claimed viscosities do not impart patentability to the claims, absent evidence to the contrary. It is expected that the viscosity of the composition disclosed by the reference having the same ingredients as the claimed composition to have the same viscosity. The art suggests adding viscosity enhancer to the composition impregnated into pad.

The woven material does not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the non-woven pad impregnated with composition comprising benzoyl peroxide in an emulsion in a container as disclosed by the reference, and adjust the viscosity motivated by the desire of the reference to obtain viscous fluid to be absorbed into the pad, as also desired by applicants, with reasonable expectation of having pad that deliver active benzoyl peroxide when wiped to the skin.

Issue 6:

The rejection of claims 4, 5, 34, and 35 as being unpatentable under 35 U.S.C. §103(a) over the '642 Patent in view of the '766 Patent.

The teachings of the references are discussed above, however, US '642 does not teach the particle size as claimed in claims 4, 5, 34 and 35.

US '766 teaches particles sizes of the emulsion are preferred to be between 0.2 and 200 micron.

Art Unit: 1615

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the emulsion disclosed by US '642 with particle sizes between 0.2 and 200 micron motivated by the teaching of US '766 that this range of droplet size is preferred for emulsion impregnated in a pad to deliver active agents to the skin, with reasonable expectation of having emulsion having droplet sizes of 0.2 and 200 micron impregnated in a pad that deliver active ingredients to the skin with great success.

Issue 7:

The rejection of claim 15 as being unpatentable under 35 U.S.C. § 103(a) over the '766 Patent in view of the '642 Patent.

The teachings of the references are discussed above, however, US '766 does not teach the package as claimed in claim 15.

US '642 teaches package as claimed in claim 15 as not prone to premature rupture but provides ready dispensing of the package contents.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pad impregnated with active agent in an emulsion and contained in a container as disclosed by US '766, and replace the container by the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having pad containing active agent in an emulsion and

Art Unit: 1615

packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Issue 8:

The rejection of claims 1-18, 34, and 35 as being unpatentable under 35 U.S.C. § 103 (a) over the ' 145 Patent in view of the '642 Patent.

US '145 teaches nonwoven substrate impregnated with composition in the form of an emulsion comprising active agent such BPO, insoluble, erythromycin, soluble, neomycin, antifungal (abstract; col.6, lines 37-38, 45; col.7, lines 7, 14-15). The emulsion is either water/oil or oil/water emulsion (col.3, lines 35-44). The composition has viscosity preferably below 150 mPa.s in order to be suitable to impregnate the substrate (col.3, lines 24-28). The mean size of the globules of the emulsion is between 50-1000 microns in order to be suitable to impregnate the substrate (col.7, lines 63-67).

However, US '145 does not teach the impregnated substrate is contained in a container.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate

Art Unit: 1615

impregnated with active agent in an emulsion as disclosed by US '145, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Issue 9:

The rejection of claims 4, 5, 8-12, 34, and 35 as being unpatentable under 35 U.S.C. §103(a) over the '642 Patent in view of the '145 Patent.

The teachings of the references are discussed above.

US '642 does not teach the particle sizes and viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '642, and adjust the droplet sizes of the emulsion between 50-1000 microns and the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising

Art Unit: 1615

substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Issue 10:

The rejection of claims 8-12 as being unpatentable under 35 U.S.C. §103(a) over the '766 Patent in view of the ' 145 Patent.

The teachings of the references are discussed above.

US '766 does not teach the viscosity of the emulsion, which is taught by US '145.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by US '766, and adjust the viscosity of the emulsion to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that this viscosity is suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a packaged article comprising substrate impregnated with emulsion having viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

Issue 11:

The rejection of claims 1-18, 34, and 35 as being unpatentable under 35 U.S.C. §103(a) over the '855 Patent in view of the '642 Patent.

US '855 teaches article for delivering active agents to the skin comprises woven or nonwoven substrate impregnated with composition in the form of emulsion comprising BPO as preferred active agent, antifungal, water soluble agents (abstract; col.6, lines 13-17; col.17, lines 30-31, 42, 55-57; col.18, lines 18, 30-40; col.25, lines 66-67; col.26, lines 19-26; col.55, lines 37-67). The composition further comprises material to adjust the viscosity the composition remains on the substrate (col.49, lines 35-50).

US '855 does not teach the article in a container, or particle sizes or the viscosity of the composition.

It is implied by the teaching of the reference that wipes and substrates impregnated with liquid composition are packaged in containers.

US '642 teaches a container for substrate impregnated with a liquid composition, as discussed above.

The claimed particle sizes and viscosity do not impart patentability to the claims because the art recognized the desire to have viscosity of the impregnated composition enough to retain the composition in the pad, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '855, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with

Art Unit: 1615

active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Issue 12:

The rejection of claims 4, 5, 8-12, 34, and 35 as being unpatentable under 35 U.S.C. §103(a) over the '855 Patent in view of the '642 Patent and further in view of the '145 Patent.

Although the cited references recognized the importance of changing the viscosity of the composition to allow the composition to remain on the substrate, the combined teaching of US '855 and US '642 does not teach the exact particle sizes and viscosities as claimed by applicants.

US '145 teaches the same ranges of particle sizes and viscosity of the composition because and teaches that these parameters are suitable for impregnating the composition into a substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising woven or nonwoven substrate impregnated with active agent in an emulsion and contained in a container as disclosed by the combined teachings of US '855 and 642, and adjust the droplet sizes of the emulsion between 50-1000 microns and the viscosity to below 150 mPa.s as disclosed by US '145, motivated by the teaching of US '145 that these parameters are suitable to allow the emulsion to impregnate the substrate, with reasonable expectation of having a

Art Unit: 1615

packaged article comprising substrate impregnated with emulsion having particle sizes of 50-1000 micron and viscosity less than 150 mPa.s wherein the composition impregnates the substrate and retained in there successfully till time of use.

(10) Response to Argument

Response to Arguments Regarding Issue 2

The rejection of claims 1, 2, 6, 7, 14-18 under 35 U.S.C. 102(b) as being anticipated by US 5,562,642 ('642):

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants argue that US '642 does not anticipate the claims because it does not teach the claimed viscosity, and viscosity is not inherent as it is determined by identity of the ingredients and their quantity. US '642 fails to teach controlling the viscosity of the composition to be low enough to penetrate the pad and high enough to be retained in the pad.

In response to this argument against the anticipatory rejection over US '642, it is argued that claim 1 and dependent claims, that included in this rejection, do not recite any active agent or any ingredient of the emulsion. Claim 1 and the dependent claims included in this rejection do not recite any specific viscosities, other than the functional language concerning viscosity. Therefore, US '642 anticipates at least claim 1, and dependent claims 2, 6, 7, 14-18. The viscosity is an inherent for the specific composition having specific ingredients in certain amounts, as appellants admit, and since the claims

Art Unit: 1615

do not recite any specific composition for the emulsion and consequently no amounts, then the reference anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition. US '642 recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate, as appellants have done. Since the essential elements of the '642 composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion capable to impregnate a pad, then '642 composition has the same physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, depending on the insoluble drug and emulsion composition. The reference teaches materials having viscosities are included in the composition, col.12, lines 54-64, and further teaches semiliquid composition, col.12, lines 6-7. Therefore, the reference implied viscous composition.

As such, it is the examiner's position that the composition advanced by '642 anticipates the compositions enumerated in the instant claim set. It has been held that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition

Art Unit: 1615

does not render the old composition new to the discoverer. *See Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

a. Group 2 – Claim 2

Appellants argue that '642 Patent does anticipate claim 2 because it does not describe a viscosity that is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

In response to this argument that, it is argued that the limitation of “delivery of the composition when the pad is wiped to the skin” is directed to the intended use of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case the pad disclosed by US '642 is capable of delivering the impregnated composition to the skin, therefore it anticipates claim 2.

Response to Arguments Regarding Issue 3

The rejection of claims 1, 2, 6, 7, 14, 16-18 under 35 U.S.C. 102(b) as being anticipated by US 6,183,766 ('766):

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants argue that US '766 failed to teach the claimed particle sizes and the particle sizes are the those of the microemulsion of the composition, and not the

active agents. The reference does not teach the claimed viscosity, and teaches viscosity with respect to specific ingredient and not the viscosity of the final composition. US '766 fails to teach controlling the viscosity of the composition to be low enough to penetrate the pad and high enough to be retained in the pad.

In response to the argument regarding the particle sizes, appellants' attention is directed to the claims included under the anticipatory rejection over US '766 that do not include any claims directed to particle sizes.

Additionally, regarding arguments against the viscosity, it is argued that claim 1 does not recite any active agent or any ingredient of the emulsion. Claim 1 and the dependent claims included in this rejection do not recite any specific viscosities, other than the language concerning functional viscosity. Therefore, US '766 anticipates at least claim 1, and dependent claims 2, 6, 7, 14, 16-18. The viscosity is an inherent for the specific composition having specific ingredients in certain amounts, as appellants admit, and since the claims do not recite any specific composition for the emulsion and consequently no amounts, then the reference anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition. US '766 recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate (col.4, lines 33-37), as applicants have done. Since the essential elements of the '766 composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion, then '766 composition has the same physiochemical properties as the composition set forth

Art Unit: 1615

in the instant application, such as viscosity of the composition, depending on the insoluble drug and the emulsion composition. The reference teaches materials having viscosities are included in the composition, col.6, lines 30-50. Therefore, the reference implied viscous composition.

As such, it is the examiner's position that the composition advanced by '766 anticipates the compositions enumerated in the instant claim set. It has been held that the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer. *See Atlas Powder versus Ireco*, 51 USPQ 2d 1943, (Fed. Cir. 1999).

a. Group 2 – Claim 2

Appellants argue that '766 Patent does anticipate claim 2 because it does not describe a viscosity that is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

In response to this argument that, it is argued that the limitation of "delivery of the composition when the pad is wiped to the skin" is directed to the intended use of the composition, and a recitation of the intended use of the claimed invention must result in

Art Unit: 1615

a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case the pad disclosed by US '766 is capable of delivering the impregnated composition to the skin, therefore it anticipates claim 2.

Response to Arguments Regarding Issue 4

The rejection of claims 3-5, 8-13, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over US '642:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants argue that the reference does not teach the viscosity of the claimed invention or the substantial retention of the composition by the pad and delivery of the active agent to the skin.

In response to this argument, it is noted that viscosity of a chemical compounds is a property that cannot be separated from the compounds and compositions having the same ingredients are expected to have the same viscosity. US '642 teaches pad impregnated by emulsion comprising active agents, and this implies that the emulsion is retained in the pad. The reference does not teach the emulsion is present separate from the pad in the container. The reference teaches materials having viscosities are included in the composition, col.12, lines 54-64, and further teaches semiliquid composition, col.12, lines 6-7. Therefore, the reference implied viscous composition. The reference further teaches the desired function because it does not teach leakage of

Art Unit: 1615

the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition. If the emulsion composition of the prior art made from the same materials as the composition of the present claims, then it is expected that the composition of the prior art will have the same viscosity as the instantly claimed composition. The rejected claim do not recite any specific materials for the emulsion composition that are responsible for the viscosity. Appellants define the viscosity of the claimed composition by its function and method of its measuring, and the burden is on applicants to show that the functions of the claimed composition resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing and measuring the claimed viscosities and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

a. Group 3 – claims 4, 5, 34, and 35

Appellants argue that US '642 does not teach the claimed particle sizes claimed by claims 4, 5, 34, and 35, and since it failed to teach viscosity, so it can not render the claims obvious.

In response to this argument, it is argued that the particles size of the active agent is the only difference between the cited references and the present claims, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes, since the art teaches using granules or powders,

Art Unit: 1615

and implies retention of the granules or particles in the applicator see col. 8, lines 34-35. It is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

a. Group 4 – claims 8, 9, 10, 11, and 12

Appellants argue that the specific viscosities claimed by claims 8-12 are not described by US '642 and the reference cannot render the claims obvious.

In response to this argument, appellants' attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity. Further the examiner hereby repeats the response as under the anticipatory and obviousness rejection over US '642, as set forth in this examiner's answer.

Response to Arguments Regarding Issue 5

The rejection of claims 3-5, 8-13, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over US '766:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants argue that the reference does not teach the viscosity of the claimed invention or the substantial retention of the composition by the pad and delivery of the active agent to the skin.

In response to this argument, it is noted that viscosity of a chemical compounds is a property that cannot be separated from the compounds and compositions having the same ingredients are expected to have the same viscosity. US '766 teaches pad impregnated by emulsion comprising active agents, and this implies that the emulsion is retained in the pad. The reference does not teach the emulsion is present separate from the pad in the container. The reference teaches materials having viscosities are included in the composition, col.8, lines 30-50. Therefore, the reference implied viscous composition. The reference teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition. If the emulsion composition of the prior art made from the same materials as the composition of the present claims, then it is expected that the composition of the prior art will have the same viscosity as the instantly claimed composition. The rejected claim do not recite any specific materials for the emulsion composition that are responsible for the viscosity. Appellants define the viscosity of the claimed composition by its function and method of its measuring, and the burden is on applicants to show that the functions of the claimed composition resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing and measuring the claimed materials and comparing them with the prior art inventions. See *In re Best*, 562 F.2 1252, 195 USPQ 430 (CCPA 1977); and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

a. Group 3 – claims 4, 5, 34, and 35

Appellants argue that US '766 does not teach the claimed particle sizes claimed by claims 4, 5, 34, and 35, and since it failed to teach viscosity, so it can not render the claims obvious.

In response to this argument, it is argued that the US '766 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 0.2 and 200 micron. One having ordinary skill in the art would have provided any particles within that range to be certain of its delivery through the skin pores. US '766 teaches particle sizes of the emulsion droplets is between 0.2 and 200 microns, and also teaches that the emulsion droplets act as vehicle for the lipophilic skin agents, col.4, lines 19-24, and this teaching implies that the lipophilic agents including BPO having particle sizes within this range in order to be carried by the particles of the vehicle. Further, it is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

a. Group 4 – claims 8, 9, 10, 11, and 12

Appellants argue that the specific viscosities claimed by claims 8-12 are not described by US '766 and the reference cannot render the claims obvious.

In response to this argument, appellants' attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity. Further the examiner hereby repeats the response as under the anticipatory and obviousness rejection over US '766, as set forth in this examiner's answer.

Response to Arguments Regarding Issue 6

The rejection of claims 4, 5, 34, and 35 under 35 U.S.C. 103(a) as being unpatentable over US '624 in view of US '766:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants traverse the above rejection by arguing that US '766 does not teach the particle sizes of BPO, but the sizes of the microemulsion.

In response to this argument, it is argued that the US '766 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 0.2 and 200 micron. One having ordinary skill in the art would have provided any particles within that range to be certain of its delivery through the skin pores. US '766 teaches particle sizes of the emulsion droplets is between 0.2 and 200 microns, and also teaches that the emulsion droplets act as vehicle for the lipophilic skin agents, col.4, lines 19-24, and this teaching implies that the lipophilic agents including BPO having particle sizes within this range in order to be carried by the particles of the vehicle. Further, it is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result

Art Unit: 1615

effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments Regarding Issue 7

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '642:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants argue that US '642 and US '766 failed to teach the claimed viscosity and if combined, they fail to teach every element of the claimed invention.

In response, it is argued that US '766 is combined with US '642 to reject claim 15 that is directed to specific materials of the container that is not disclosed by US '766 but disclosed by US '642. In response to the argument regarding the viscosity, examiner hereby repeats the response as under the anticipatory and obviousness rejection over US '642 and US '766, as set forth in this examiner's answer.

Response to Arguments Regarding Issue 8

The rejection of claims 1-18, 34, and 35 under 35 U.S.C. 103(a) as being unpatentable over US 6,784,145 in view of US '642:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants hereby repeat the argument regarding US '642. Appellants further argue that US '145 teaches viscosity below the claimed viscosities, and silent

Art Unit: 1615

regarding the particle sizes of the active agent and disclosed only the particle sizes of the globules of the fatty phase of the oil-in-water emulsion.

The examiner hereby repeats the response regarding argument against US '642 as set forth in this examiner's answer.

In response to this argument regarding US '145 teaches viscosity lower than the claimed viscosity, it is argued that the claims do not recite any ingredient of the emulsion. The reference teaches the desired function of the viscous composition because it does not teach leakage of the emulsion from the pad and teaches impregnation of the pad with the emulsion composition. The reference teaches viscosity measured by different apparatus and under different circumstances than instantly claimed method and circumstances. Additionally, the present claims recite the viscosity is measured for 60 seconds, while US '145 teaches viscosity less than 150 mPa.second., therefore, when the present viscosity measured for one second will overlap with the viscosity disclosed by US '145. US '145 recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate, as appellants desired to do. Since the essential elements of the '145 composition are similar to the instant compositions, i.e. composition comprising insoluble active agent and emulsion capable to impregnate a pad, then '145 composition has the same physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, depending on the ingredients of the emulsion.

In response to the argument regarding the particle sizes, it is argued that the US '145 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 50 and 1000 micron and also teaches that the emulsion droplets are suitable for impregnation in the substrate, col.7, lines 53-57, and this teaching implies that the active agents including BPO having particle sizes within this range in order to be impregnated into the substrate. Further, one having ordinary skill in the art would have provided any particles within that range to be certain of its impregnation in the substrate and its delivery through the skin pores. Further, it is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

a. Group 2 – Claim 2

Appellants argue that US '145 and US '642 do describe a viscosity that is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

In response to this argument that, it is argued that the limitation of "delivery of the composition when the pad is wiped to the skin" is directed to the intended use of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

Art Unit: 1615

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case the pad disclosed by the combination of US '145 and US '642 is capable of delivering the impregnated composition to the skin, therefore the combination renders claim 2 obvious.

b. Group 3 – claims 4, 5, 34, and 35

Appellants argue that the combination of US '145 and US '642 does not teach the claimed particle sizes claimed by claims 4, 5, 34, and 35, and since it failed to teach viscosity, so it can not render the claims obvious.

In response to the argument regarding the particle sizes, it is argued that the US '145 recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 50 and 1000 micron and also teaches that the emulsion droplets having such sizes are suitable for impregnation in the substrate, col.7, lines 53-57, and this teaching implies that the active agents including BPO having particle sizes within this range in order to be impregnated in the substrate and delivered to the skin. Further, one having ordinary skill in the art would have provided any particles within that range to be certain of its impregnation into the substrate and its delivery through the skin pores. Further, it is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is

Art Unit: 1615

ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

c. Group 4 – claims 8, 9, 10, 11, and 12

Appellants argue that the specific viscosities claimed by claims 8-12 are not described by the combined teachings of US '145 and US '642 and cannot render the claims obvious.

In response to this argument, appellants' attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity. Further the examiner hereby repeats the response rejections over US '642 and its combination with US '145, as set forth in this examiner's answer.

Response to Arguments Regarding Issue 9

The rejection of claims 4, 5, 8-12, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over US '642 in view of US '145:

Appellant's arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants here by repeat the arguments regarding combining US '642 and US '145 as under "Issue 8".

In response, the examiner hereby repeats the arguments as under "issue 8" and sections "b, group 3" and "c, group 4" under "Issue 8" as set forth in this examiner's answer.

Response to Arguments Regarding Issue 10

The rejection of claims 8-12 under 35 U.S.C. 103(a) as being unpatentable over US '766 in view of US '145:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants hereby repeat the same arguments against US '766 and US '145 as set forth.

In response, the examiner repeats the responses as set forth in this examiner's answer regarding US '766 and US '145.

Response to Arguments Regarding Issue 11

The rejection of claims 1-18, 34, and 35 under 35 U.S.C. 103(a) as being unpatentable over US 6,338,855 ('855) in view of US '642:

Appellants' arguments filed 70/06/2007 have been fully considered but they are not persuasive. Appellants repeats the arguments regarding US '642, particle sizes and viscosity, and further argue that US '855 teaches dry pad that is wetted before use while the present invention is wet composition retained in the pad.

In response to this argument, the examiner hereby repeats the response regarding US '642, particle sizes and viscosities as set forth in this examiner's answer.

Regarding US '855, it is argued that the present claims are directed to an article comprising pad and composition impregnated into the pad, and all the elements of the article are disclosed by the combined teachings of the references. US '855 teaches nonwoven substrate impregnated with composition in the form of emulsion, see col.26,

Art Unit: 1615

lines 21-25, comprising BPO, as instantly claimed, and impregnation of the substrate with emulsion implies wet pad. US '855 teaches substantially dry pad that is wetted before use. Wetting of the pad of the prior art before use does not constitute a teaching away from the present claims and the product of the prior art makes the present claims obvious because wetting of the pad before use is directed to intended use of the pad, and the present claims do not exclude wetting of the pad before use. US '642 in this rejection is relied upon for its solely teaching of the container. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising nonwoven substrate impregnated with active agent in an emulsion as disclosed by US '855, and package the article in the container disclosed by US '642 that comprises aluminum foil layer in contact or sealed with thermoplastic layer, motivated by the teaching of US '642 that this package is not prone to premature rupture but provides ready dispensing of the package contents, with reasonable expectation of having substrate impregnated with active agent in an emulsion and packaged in package comprises aluminum foil layer in contact or sealed with thermoplastic layer that is not prone to premature rupture but provides ready dispensing of the package contents.

Regarding the viscosity and the particle sizes, the examiner here by repeats the response to argument against US '642 as set forth in this examiner's answer. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where

Art Unit: 1615

the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

a. Group 2 – Claim 2

Appellants argue that US '855 combined with US '642 do describe a viscosity that is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

In response to this argument that, it is argued that the limitation of “delivery of the composition when the pad is wiped to the skin” is directed to the intended use of the composition, and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case the pad disclosed by the combination of US '855 and US '642 is capable of delivering the impregnated composition to the skin, therefore the combination renders claim 2 obvious.

b. Group 3 – claims 4, 5, 34, and 35

Appellants argue that the combination of US '855 and US '642 does not teach the claimed particle sizes claimed by claims 4, 5, 34, and 35, and since it failed to teach viscosity, so it can not render the claims obvious.

In response to the argument, it is the examiner's position that the particle sizes are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). US '642 teaches particles impregnated in the applicator and desired to add viscosity enhancing agents.

c. Group 4 – claims 8, 9, 10, 11, and 12

Appellants argue that the specific viscosities claimed by claims 8-12 are not described by the combined teachings of US '855 and US '642 and cannot render the claims obvious.

In response to this argument, appellants' attention is directed to the broadness of the claims that recite no specific ingredients resulting in the claimed viscosity. Further the examiner hereby repeats the response rejections over US '642 as set forth in this examiner's answer.

Response to Arguments Regarding Issue 12

The rejection of claims 4, 5, 8-12, 34, and 35 under 35 U.S.C. 103(a) as being unpatentable over US '855 in view of US '642 and further in view of US '145:

Appellants' arguments filed 07/06/2007 have been fully considered but they are not persuasive. Appellants repeat the argument that the prior art does not teach the

Art Unit: 1615

claimed viscosity and particle sizes, and one of ordinary skill in the art would not be motivated to combine the references.

Regarding the viscosity and the particle sizes, the examiner hereby repeats the responses as set forth under issue 11 in this examiner answer. It is also argued that it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the particle sizes and viscosity, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233. In response to appellants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, in this case one having ordinary skill in the art at the time of the invention would have provided pad impregnated with emulsion and BPO in a container as disclosed by the combined teaching of the references, and adjust the viscosity and particle sizes of the active agents according to the intended use of the article.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

Art Unit: 1615

evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Isis Ghali,

Examiner



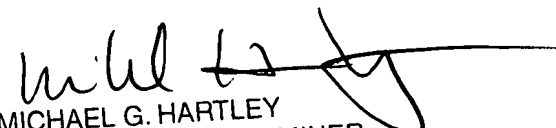
Conferees:

Michael Woodward,

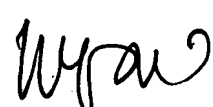
SPE 1615

Michael Hartley,

SPE 1618



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600